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(71) Applicant(s):
Mavrik Dental Systems Ltd
(Incorporated in Israel)
22 Hatzlil Street, Ra'anana 43396, Israel

(72) Inventor(s):
Daniel Sanders

(74) Agent and/or Address for Service:
Fresh IP
St John's Innovation Centre, Cowley Road,
Cambridge, CB4 0WS, United Kingdom

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(56) Documents Cited:
WO 2013/039906 A1 **WO 2008/137069 A2**
US 4790752 A1 **US 20140080082 A1**
US 20060246400 A1

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INT CL **A61C, B29C**
Other: **ONLINE: WPI EPODOC**

(54) Title of the Invention: **An anatomical drape device**
Abstract Title: **Anatomical drape apparatus and method**

(57) An anatomical drape apparatus is made of an elastomeric material and a curing agent. An associated second such apparatus further features liquid impermeability and gas permeability. An associated method of making the apparatus features adding a first soluble additive to an elastomeric material, moulding the material, adding a solvent to dissolve and remove the additive thus forming voids, and introducing a second additive, which is a curing agent, into at least some of the voids. The apparatus may have the advantage that it may be cured in situ to a close form of the anatomical features, such as teeth and gums, that it covers, such as by light or heat. This may form an improved fluid barrier for medicament applied either inside or outside of the apparatus. The apparatus may further feature holes for teeth to pass through.

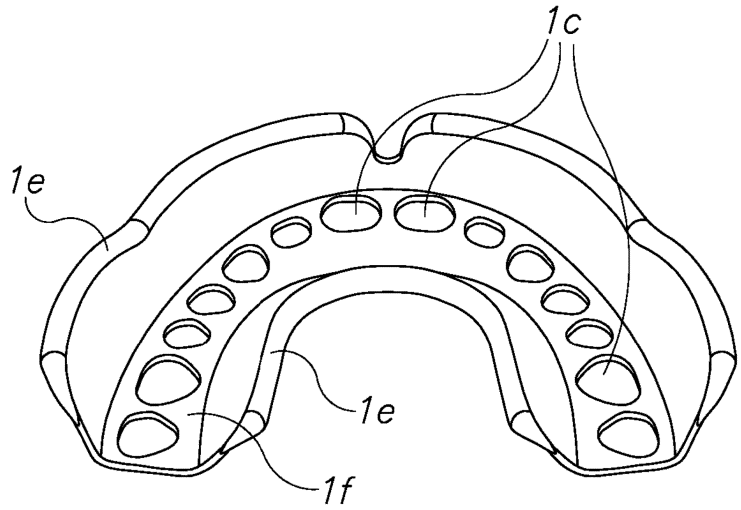

FIG.1B

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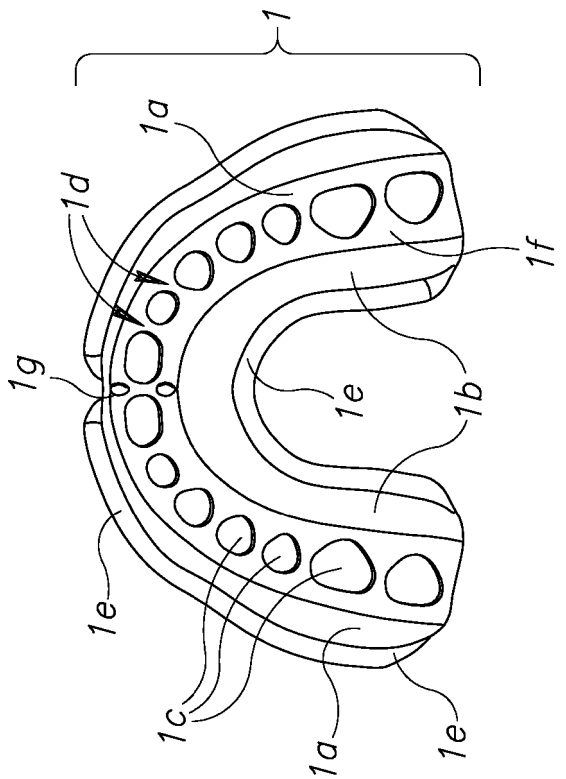

FIG.1A

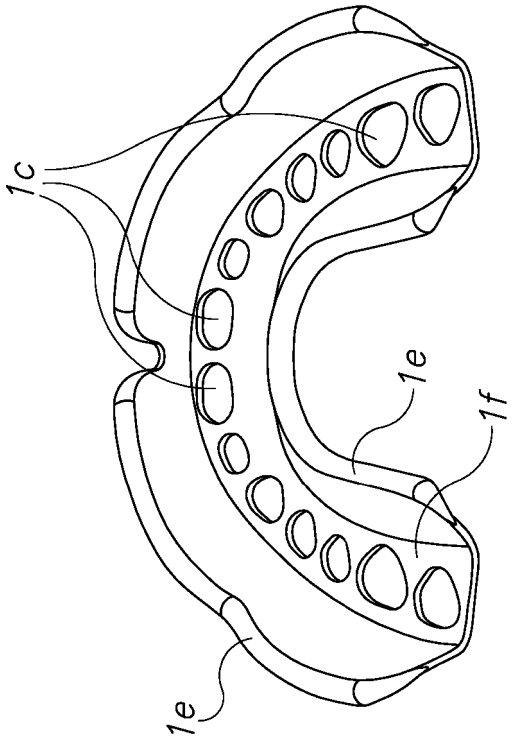

FIG.1B

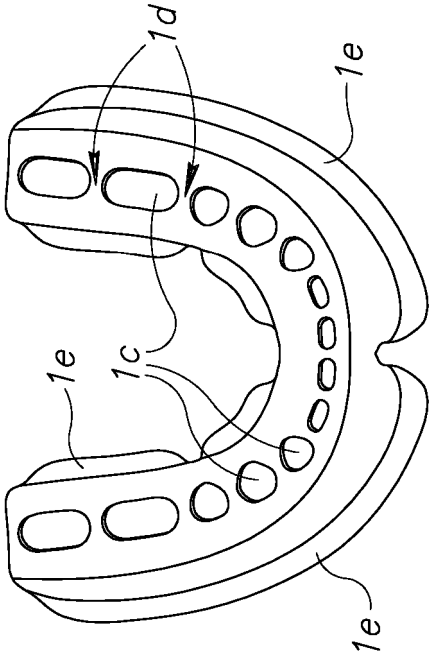

FIG.1C

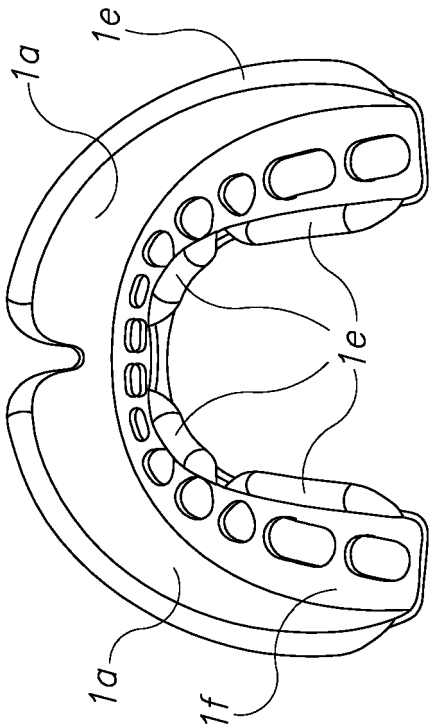

FIG.1D

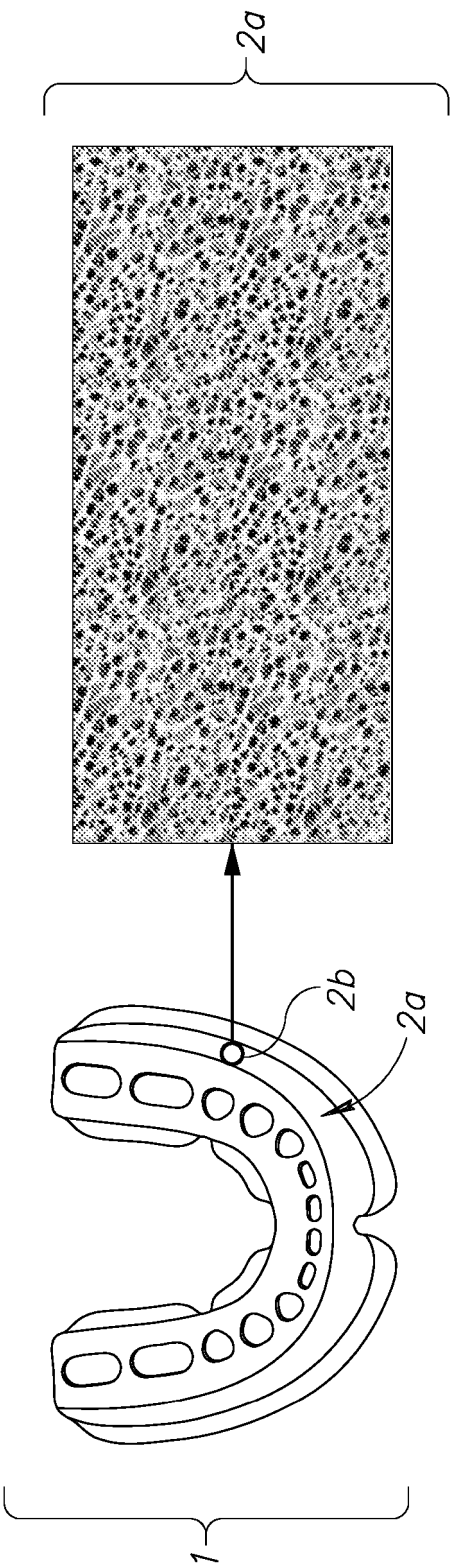

FIG.2A

FIG.2B

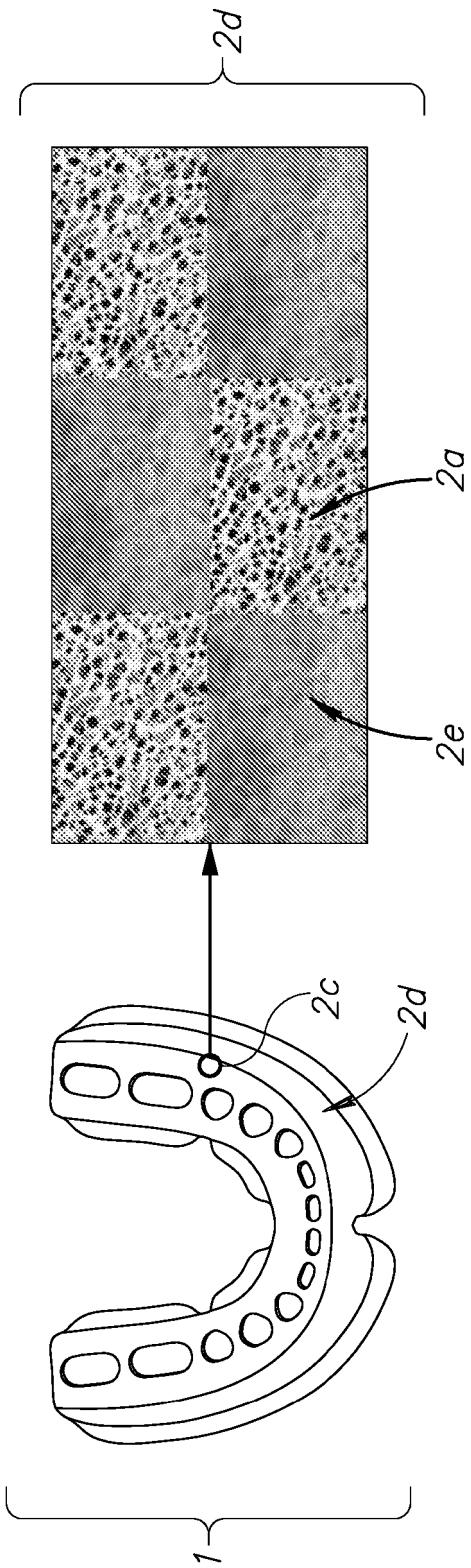

FIG.2C

FIG.2D

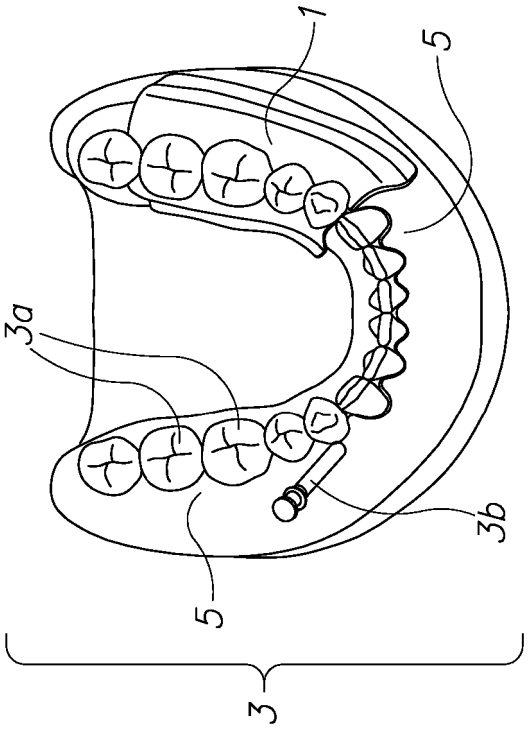

FIG.3A

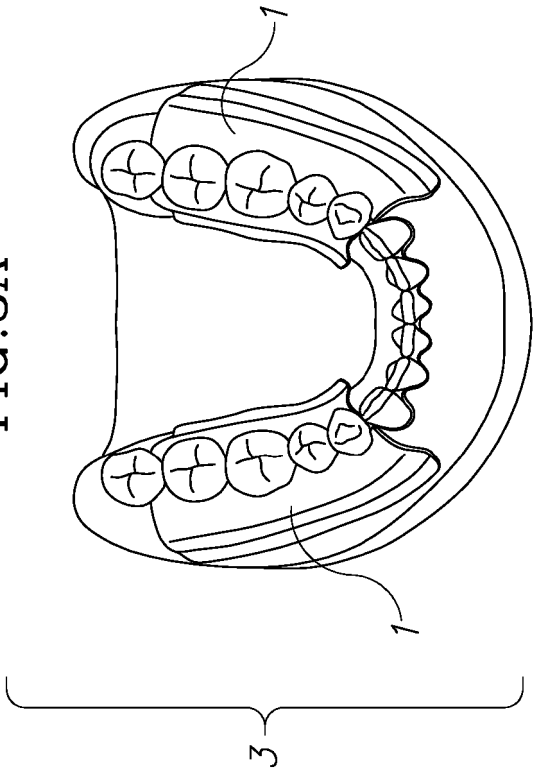

FIG.3B

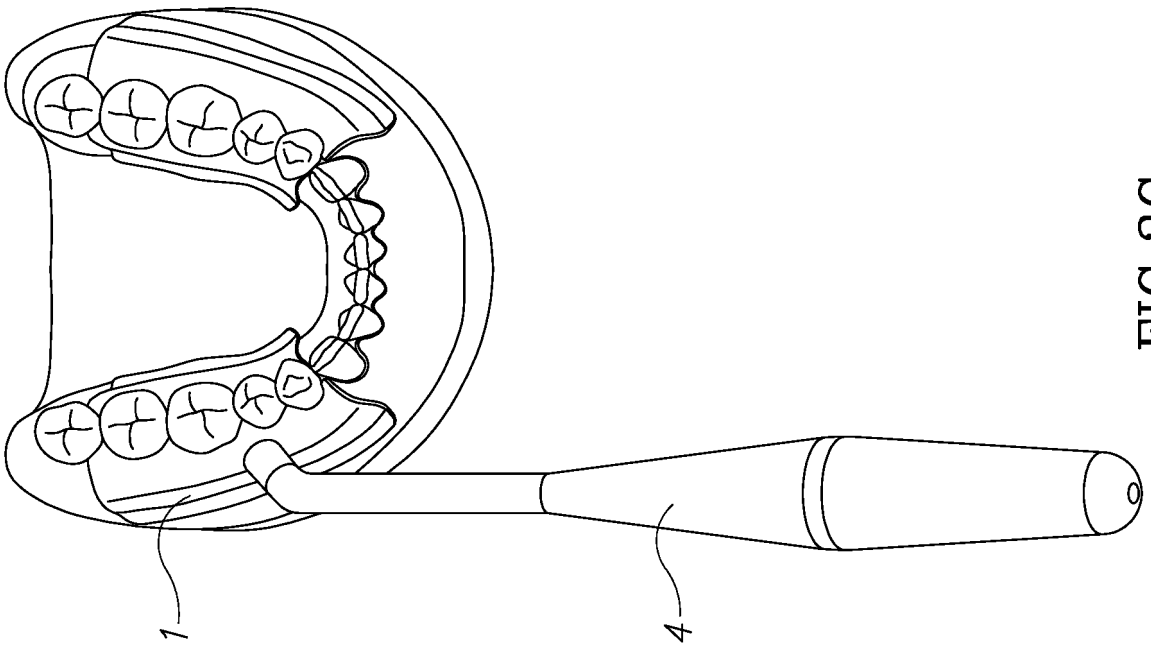

FIG.3C

AN ANATOMICAL DRAPE DEVICE

FIELD OF THE INVENTION

[01] The present invention relates to methods and devices useful in providing drapes or covers for anatomical parts, such as during treatment of the parts, particularly but not exclusively to oral drapes for dental treatments.

BACKGROUND OF THE INVENTION

[02] In dental medicine, many treatment materials are typically placed within the oral cavity on the hard (teeth) tissues and soft (inner mucosal epithelium of the cheek, lips, and gingiva and the tongue) tissues.

[03] These treatment materials are placed topically on these tissues or may be inserted (injected) in the space between them, for example, in the naturally occurring sulcus at the tooth/gum line.

[04] These treatment materials are typically applied to the tissues in an "open" manner, namely, without any covering material or containment device. This significantly reduces their desired therapeutic effect as the materials are immediately exposed to saliva contamination (containing numerous pathogenic microorganisms) and salivary washout (or fluid/solids ingestion washout) in a very short time. This time range can be as short as a few seconds to around 10 minutes or more, depending on salivary flow, the viscosity of the treatment material or whether the patient ingests solids or liquids after application of the treatment material.

[05] Additionally, currently known devices use a cover device that covers both the teeth and the gums. These are typically custom made to a specific patient using the following fabrication method. Dental molds are taken of the patient's teeth and surrounding gums and dental stone cast models are poured and allowed to harden. These cast models are removed from the molds and a vacuum-formed thin plastic custom made tray for that specific patient is formed and trimmed to

cover over both the teeth and a narrow portion of the surrounding gums. These typically leak the treatment material out of them and also allow saliva to seep inside of them as the stiff material of the tray is difficult to adapt closely to the undulating and varied topography of the teeth and surrounding gums of each individual patient which they are meant to cover.

[06] Additionally, patches onto whose inner surface a thin layer of treatment material has been adhered are used to cover small areas of the gum tissue. Due to their size they can only treat very limited areas of the soft tissues of the oral cavity and cannot be used to treat the teeth as they cannot be adhered to the teeth structure. They are also easily dislodged by the tongue or contact with the inner cheek and lip muscles.

[07] It is an object of the present invention to provide an improved device that aims to overcome or at least alleviate the above mentioned drawbacks.

SUMMARY OF THE INVENTION

[08] In accordance with a first aspect of the present invention, there is provided an anatomical drape for covering a treatment area of an anatomical part, the drape comprising an elastomeric material capable of conforming to the contours of the anatomical part and including a curing agent wherein activation of the curing agent causes hardening of the material to set the drape in a configuration conforming to the anatomical part.

[09] The anatomical part preferably comprises an oral anatomy. However, it is to be appreciated that a drape may be provided to cover any anatomical part, such as a limb (or portion of a limb).

[010] More preferably, the drape conforms to a gum ridge anatomy with the drape forming an enclosed protective cover over the gum ridge. The drape may comprise a partial or full U-shaped arch which is then tailored to the actual oral anatomy to provide a high level of conformity. The drape, in some embodiments, may be provided with pre-perforated holes for easy removal and passage of teeth there-through or pre-configured cut-out holes may be provided of varying shapes and dimensions for receipt of teeth there-through whereby the teeth remain substantially uncovered and exposed to the oral cavity.

[011] The preformed shape of the drape is formed to generally conform to the shape of the oral

cavity or other body part to facilitate easy and rapid insertion and removal of the drape from the target area.

[012] The curing agent may only partially impregnate the elastomeric material, for example being scattered at intervals throughout the elastomeric material. This will provide a semi-rigid drape that conforms to a particular individual anatomy while allowing its removal and enhancing comfort to the user.

[013] Preferably, the elastomeric material of the drape is substantially liquid impermeable and gas permeable, both before and after curing. In some embodiments, the elastomeric material has high tear strength properties.

[014] More preferably, the drape is comprised at least partially of a foam elastomeric material, preferably being then further treated to enhance the voids, wherein at least some of the enhanced voids in the foam are provided with the curing agent. Any suitable curing agent may be used but preferably the curing agent is activated by an external source, such as heat and/or light.

[015] Suitable elastomeric materials include, but are not limited to TPE's (thermoplastic elastomers; TPU's (thermoplastic urethanes); elastomeric silicones (RTV, HTV, LSR), the material preferably being both substantially liquid impermeable and gas permeable (i.e., breathable). Preferably, the material contains millions of micro-pores per square cm.

[016] The drape may include one or more treatment material layers on at least one surface of the drape, for example for neutralizing treatment materials and/or gum treatment materials, such as therapeutic or medicinal agents. The materials are preferably provided on the inner surface of the drape.

[017] According to additional embodiments a port may be provided for receiving a tool, such as a syringe for delivery of therapeutics to a treatment area.

[018] A second aspect of the present invention provides a kit of parts for installing an anatomical drape, the kit comprising a drape according to the first aspect of the present invention and a light source, optionally with at least one further drape and/or a therapeutic or other treatment source.

[019] A third aspect of the present invention provides a method for the manufacture of an anatomical drape, preferably being a drape according to the first aspect of the present invention,

the method comprising the steps of: (a) adding a soluble additive to an elastomeric material; (b) molding the material to conform generally to the contours of an anatomical part; (c) adding a solvent to dissolve and remove the additive thereby forming voids in the elastomeric material; and (d) introducing a second additive into at least some of the voids.

[020] The soluble additive may comprise grit of any desired size for forming voids of a corresponding size. Preferably, the additive has a low or high melting point to cause flow or allow compression of material into a desired mold to cast the drape into a desired configuration. The second additive preferably comprises a curing agent, such as a light or UV light activated curing agent, wherein the drape may be tailored to the specific contours of a particular anatomical part and set/hardened in this configuration by activation of the curing agent.

[021] Step (d) preferably comprises spraying, dipping, or injecting of the second additive to allow its introduction into the voids of the material. Preferably, addition and curing of the second additive retains the breathable properties of the drape while preserving its impermeability to fluids.

DESCRIPTION OF THE DRAWINGS

[022] The principles and operation of the system, apparatus, and method according to the present invention may be better understood with reference to the drawings, and the following description, it being understood that these drawings are given for illustrative purposes only and are not meant to be limiting, wherein:

[023] FIG. 1A is a top view of an upper full dental arch oral drape, according to some embodiments;

[024] FIG. 1B is a bottom view of the upper full dental arch oral drape 1 of FIG. 1A, wherein are depicted the same features as in FIG. 1A, according to some embodiments;

[025] FIG. 1C is a is a top view of one embodiment of a lower full dental arch oral drape 1, according to some embodiments;

[026] FIG. 1D is a bottom view of the lower full dental arch oral drape 1 of FIG. 1C, wherein are depicted the same features as in FIG. 1C, according to some embodiments;

[027] FIG. 2A is a top view of the lower full dental arch oral drape 1 of FIG.'s 1C and 1D, wherein is depicted a delineated area of the weave-like spongy body surface 2a marked by a circle 2b, and further illustrated in an expanded view in FIG.2B, according to some embodiments.

[028] FIG. 2B is a magnified view of the microstructure of the oral drape 1, wherein are depicted a weave-lie spongy structure 2a that may include a myriad of three dimensional spongy threads and voids between the spongy threads;

[029] FIG. 2C is a top view of the lower full dental arch oral drape 1 of FIG.'s 1C and 1D, wherein is depicted a delineated area of the body surface 2a, marked by a circle 2c, according to some embodiments;

[030] FIG. 2D is a magnified view of one embodiment of the microstructure of the oral drape 1, after partial impregnation of an additive according to some embodiments;

[031] FIG. 3A is a top view of a lower full dental arch 3 which depicts the teeth 3a of the arch 3, according to some embodiments, of a segmental oral drape 1, and a syringe for the applying of medicinal therapeutics to the teeth 3a, the surrounding gums 5, or both;

[032] FIG. 3B is the top view illustrated in FIG. 3A, wherein is depicted a second segmental oral drape 1 fitted over the teeth and their surrounding gums 5 so as to cover over and contain the treatment material previously applied in FIG. 3A, according to some embodiments; and

[033] FIG. 3C is the top view of illustrated in FIG. 3B wherein is depicted a light source 4, directed to catalyze and so harden the impregnated curable material 2e, according to some embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[034] The following description is presented to enable one of ordinary skill in the art to make and use the invention as provided in the context of a particular application and its requirements. Various modifications to the described embodiments will be apparent to those with skill in the art, and the general principles defined herein may be applied to other embodiments. Therefore, the present invention is not intended to be limited to the particular embodiments shown and

described, but is to be accorded the widest scope consistent with the principles and novel features herein disclosed. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

[035] The word "drape" as used herein may encompass various protective materials with or without adhesives that may be utilized to cover, dress or place over a target area or object(s) while undergoing a treatment, to cover or protect a target area, and optionally prevent the flow of liquids or materials from or to the target area.

[036] FIG. 1A is a top view of an upper full dental arch oral drape, according to some embodiments; 1, wherein are depicted the buccal side wall 1a of the drape 1, the lingual side 1b of the drape 1, and the varying size and diameter holes 1c which allow the drape 1 to be placed over the teeth (so as to allow the teeth to remain substantially not covered by the oral drape and exposed to the oral cavity) and fitted over the surrounding gums to substantially cover them. Also depicted are the interdental tension bridges 1d which fit into the interproximal spaces between adjacent teeth and provide a substantial circumferential fit of the drape 1 around the teeth, the discontinuous outer rim roll 1e, which may stiffen to a degree the form of the oral drape and may aid in grasping its edges to facilitate its insertion onto the target treatment area. Also depicted is the crestal gum ridge surface 1f, and the midline reference bumps 1g, to visually and tactilely aid in positioning and alignment of the oral drape to the target treatment area.

[037] FIG. 1B is a bottom view of the upper full dental arch oral drape 1 of FIG. 1A, wherein are depicted the same features as in FIG. 1a, according to some embodiments.

[038] FIG. 1C is a is a top view of one embodiment of a lower full dental arch oral drape 1, according to some embodiments, wherein are depicted the buccal side wall 1a of the drape 1, the lingual side 1b of the drape 1, and the varying size and diameter holes 1c which allow the drape 1 to be placed over the teeth (so as to allow the teeth to remain substantially not covered by the oral drape and exposed to the oral cavity) and fitted over the surrounding gums. Also depicted are the interdental tension bridges 1d, the discontinuous outer rim roll 1e, the crestal gum ridge surface 1f, and the midline reference bumps 1g.

[039] FIG. 1D is a bottom view of the lower full dental arch oral drape 1 of FIG. 1C, wherein are depicted the same features as in FIG. 1C, according to some embodiments.

[040] FIG. 2A is a top view of the lower full dental arch oral drape 1 of FIG.'s 1C and 1D, wherein is depicted a delineated area of the weave-like spongy body surface 2a marked by a circle 2b, according to some embodiments.

[041] FIG. 2B is a magnified view of the microstructure of the oral drape 1, wherein are depicted one possible embodiment of a weave-lie spongy structure 2a that may include a myriad of three dimensional spongy threads and voids between the spongy threads, according to some embodiments.

[042] FIG. 2C is a top view of the lower full dental arch oral drape 1 of FIG.'s 1C and 1D, wherein is depicted a delineated area of the body surface 2a, marked by a circle 2c, according to some embodiments.

[043] FIG. 2D is a magnified view of one embodiment of the microstructure of the oral drape 1, according to some embodiments, wherein are depicted a light curable material 2e, impregnated into portions of the weave-lie spongy structure 2a so as to form a pattern (e.g. a scatter pattern) surface 2d composed of areas that are impregnated with curable material 2e and ones that are not impregnated with the curable material 2e.

[044] FIG. 3A is a top view of a lower full dental arch 3 which depicts the teeth 3a of the arch 3, according to one embodiment, of a segmental oral drape 1, and a syringe 3b for the applying of therapeutics to the teeth 3a, the surrounding gums 5, or both, prior to the placement of an oral drape 1 over this area.

[045] FIG. 3B is the top view illustrated in FIG. 3A, wherein is depicted a second segmental oral drape 1 fitted over the teeth and their surrounding gums 5 so as to cover over and contain the treatment material previously applied in FIG. 3A, according to some embodiments.

[046] FIG. 3C is the top view of illustrated in FIG. 3B wherein is depicted a light source 4, directed to catalyze and so harden the impregnated curable material 2e, and so conform the oral drape 1 to the specific topography of the target treatment area and set in place the conformed oral drape 1 over the target treatment area, according to some embodiments.

[047] According to some embodiments, a dental oral drape is provided, that may include a flexible surgical arch shaped drape that is flexible to apply and to remove, that is designed to conform substantially to an anatomic area, and that is both liquid impermeable and gas

permeable. In one example, the dental oral drape is designed to conform to the gum ridge anatomy, and has pre-configured cut-out holes of various shapes and diameters for insertion over and through the teeth (if the teeth are present), and for adaptation around or near to the gum line of the teeth, for example, as described in PCT application number WO 2013/039906 A1, by the same inventor. Of course drapes as described herein may be used to cover and/or contain treatment areas besides the oral area, for example, in or on other bodily limbs or parts.

[048] In some embodiments, the device includes a dental oral drape component for protection against treatment materials (such as a whitening agent) applied to the teeth that may be exposed as well to the surrounding gum tissue of the teeth that are covered (contained) by an oral tooth and/or gum treatment device being used for a treatment cavity or cavities of a mouthpiece, for example, as described in PCT patent application number WO 2013/039906 A1, by the same inventor.

[049] In some embodiments, the dental oral drape includes a treatment material layer on one or more surfaces, wherein the treatment material is suitable for neutralizing treatment materials.

[050] In some embodiments, the device includes a dental oral drape component which includes a treatment layer on its inner surfaces for the delivery of one or more therapeutic treatment materials or medicinal materials to the gums or teeth.

[051] In some embodiments the oral drape is formed from a variety of elastomeric materials such as but not limited to: TPE's (thermoplastic elastomers; TPU's (thermoplastic urethanes); elastomeric silicones (RTV, HTV, LSR) that are substantially both liquid impermeable and gas permeable (i.e., Breathable). For example, they may contain millions of micro-porosities per sq. cm. in their structure that are naturally formed during the mixing and molding process.

[052] In some embodiments an additive material of various grit sizes that is soluble (e.g., using various solvents or even water) may be incorporated into the oral drape elastomeric materials during the drape formation process and prior to molding these elastomeric materials in a mold. In some examples, this additive may have a low or high melting point such that when either a low and/or high temperature molding process is utilized to form or mold the elastomeric material to a specific shape, these additive materials will remain embedded in the body structure of the elastomer during the molding process (e.g., which may require heating the elastomer to a either a low or high temperature to flow or compress the material into the desired mold).

[053] Examples of the additive material may include but are not limited to various sodium salts, sodium bicarbonate, potassium salts, and sugars.

[054] In a further fabrication step, the above described additive can then be removed from the structural matrix of the resultant molded elastomeric oral drape by dissolution in water or another solvent (e.g., at various temperatures and under various positive or negative air pressures, or electrically conductive conditions). This removal process of the additive particles results in a device whose three dimensional molded structure includes holes, which may be adapted to house additional elements. In one example, the drape device structure may resemble a "spongy weave like" matrix with voids or holes between the "spongy threads".

[055] In a further fabrication step, a light curable material (for example, visible or UV light catalyzed) may then be impregnated into at least a portion of the resultant voids in the drape device substrate, created from gaps where the additive was located. For example, such a light curable material may be applied by spraying, rapidly dipping or injecting (or by means of another application process) the material onto the surface of the device so as to achieve a "scatter-like" pattern of the light curable material within the oral drape structure. In some examples, this partial impregnation of at least a portion of the surface of the oral drape device with the light curable material still allows for the material of the oral drape to retain its "breathable" characteristics (gas permeability) while preserving the devices' impermeability to fluids.

[056] Examples of the light curable materials may include but are not limited to various blended mixtures of acrylate monomers, urethane acrylate oligomers, triacrylate cross linkers, plasticizers, and photo-initiators. Preferably this material is elastic and may have elongation properties of 10% or even 50% or possibly even 100% or more.

[057] According to some embodiments, this incorporated visible or UV "reinforcing matrix" can be utilized to custom shape the oral drape device to a specific patient's anatomy and substantially or partially immobilize this shape over the target area. In one example: The resultant three dimensional form can be draped over varying topography (e.g., each patient's mouth is unique) of the gum tissues (e.g., after first being pulled over the teeth in the dentulous situation), and then selectively patted or stretched down over the anatomy to achieve a high level of conformity to the individual tissue topography. The incorporated light curable material can

then be hardened around individual teeth and the gums around them by applying a readily available dental LED or UV light source to the material. In some examples the light curable materials may be selectively cured, for example by applying the light in a segmental manner to specific areas of the drape so as to immobilize the desired customized final shape to the target area.

[058] In some embodiments, the manufacturing process herein described provides for using a stock sized pre-formed (molded) three dimensionally shaped drape device (e.g., that is non-custom made for a target anatomy) that can be readily and quickly adapted to each patient's specific anatomy to provide a "custom fit" to each patient's anatomy. Such a customized drape may provide a superior substantially semi-rigid barrier that can be used, for example, in the following applications:

[059] The drape as described above may be used as a wound dressing or containment device (with or without impregnating the inner surface with a therapeutic) or as a delivery device itself (e.g., if an additional therapeutic agent is later impregnated on its inner surface as a coating in a later step of the manufacturing process) to hold a therapeutic in place onto the target area. Therapeutic applications include but are not limited to post-periodontal (gum) surgery, post-dental implant surgery, following deep debridement (cleaning) of the gum tissues (specifically the naturally occurring sulcus between the gum and teeth) of patients with gingivitis or periodontitis, oral apthous lesions, and oral viral lesions.

[060] In further embodiments, the initial form of the oral drape may substantially contain the treatment material in a more effective manner on the target treatment area, and allow for a significantly longer duration, larger quantity and/or larger surface area application of the treatment material to the applied target area as compared to the known art. This may be advantageous, for example, to substantially prevent or limit saliva contamination (filled with pathogenic bacteria) and saliva washout (dilution of the therapeutic in the salivary fluid and its removal as is the case with the prior art).

[061] According to some embodiments, the oral drape device may be placed over the teeth so as to expose the teeth to the oral cavity (if present) and substantially cover the surrounding gums after prior application (injecting) of a therapeutic treatment either onto the surface of the gum tissue, onto the tooth surface near the gum line, or into the natural (healthy or diseased) space

(sulcus) between the gums and the teeth which often (i.e. prevalence rates of 50-70% in the adult population of industrialized nations) harbor pathogenic bacteria that cause gum disease (gingivitis and periodontitis). This improved exposure of the treatment material to the target treatment area may enable enhanced effectiveness in halting progression of the gum disease or aid in regeneration of healing tissue post-surgery that may reverse the disease state or promote healing of surgically incised tissue so as to bring the gums back to a state of health.

[062] In further embodiments, if applied to the tooth structure near the gum line that may be covered by the oral drape, the treatment material may aid in more effectively re-mineralizing the demineralized (eroded) tooth structure that typically causes temperature (hot and cold) sensitivity to the teeth of patients who have these tooth erosions.

[063] In accordance with further embodiments, a drape device that has been pre-impregnated on its inner surface with a treatment material at the time of fabrication or prior to insertion in the mouth, may have substantially all the advantages of the embodiments described above, while additionally enabling delivery of the therapeutic treatment material effectively and safely to a target location. In some examples this may obviate the need to first apply a treatment material onto or into the tissue to be treated. Such an embodiment may enhance the prevention and/or minimization of saliva contamination (filled with pathogenic bacteria) and saliva washout (dilution of the therapeutic in the salivary fluid and its removal).

[064] As mentioned above, in some embodiments, the elastomeric materials used to form the pre-formed body structure of the oral draping device may be engineered to be differentially permeable (permeable to oxygen to permit "breathing" of the tissue under it and yet impermeable to fluids so as to prevent saliva contamination and washout).

[065] In still further embodiments the oral drape device described herein may enable application to a patient anatomy to act as a barrier to substantially prevent moisture contamination of the tooth structure by the surrounding soft tissues, thereby creating what is commonly known in the field of dentistry as a "dry field" (i.e. a substantially moisture-free work area), which is often a very important requirement for properly placing many dental restoratives (fillings etc.) into the teeth. In the currently described embodiment, application of the device may compliment and/or replace the typical rubber dam (typically a flat latex sheet drape), which is relatively cumbersome, time consuming to place (typically requires manually punching holes in

it to cover the teeth, placement of a clamping device on one of the teeth to keep the rubber dam in place and often attachment of the rubber dam to an external frame to keep its otherwise loose unsupported sections away from the work area). The currently known rubber dam devices are typically uncomfortable for the patient and challenging for usage by the dentist for the above reasons.

[066] In accordance with some embodiments, the oral drape device may be fabricated in full arch forms to cover all the teeth and surrounding gums of the upper or lower dental arches. It can also be fabricated to cover segments (e.g., anterior or posterior) or fabricated to cover a single tooth or only a few teeth and adjacent surrounding gum tissue.

[067] In additional embodiments, the drape device may be applied outside of the oral cavity, for example, by molding the material to a different shape (such as a sleeve or cuff), for covering a body part (e.g., the knee, elbow, ankle, neck etc.), by manually adapting so as to conform portions of the material to the surfaces of that body part so as to achieve excellent conformity and a "custom fit" of the material to that body surface, and then hardening at least some of the impregnated light curable material incorporated in its surfaces so as to achieve a semi-rigid cast or drape.

[068] In further embodiments the drape device may also be formed in stock sized molded sections (e.g., to cover a limb, a portion of a limb, or a portion of the torso) and so may be used to treat a body area. In one example the drape device may be used to treat skin burn victims by effectively covering and partially immobilizing the damaged body parts substantially (especially in areas where there is normally joint movement of that body part), without the need for applying heavy plaster-type casts. In another example this application may be used where a treatment material may have first been applied separately to the damaged tissue or the treatment material may have been applied to the inner surface of the device prior to placing and adapting the device in a "custom fit manner to the desired treatment area".

[069] In still further embodiments, the treatment material to be applied with the drape device may be formulated so that its therapeutic effect is in a time released manner or the treatment material may be first inserted into a manually or electronically controlled pumping device that has first been placed on the treatment area surface and then covered with the therapeutic draping device of the present invention.

[070] The foregoing description of the embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. It should be appreciated by persons skilled in the art that many modifications, variations, substitutions, changes, and equivalents are possible in light of the above teaching. It is, therefore, to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

CLAIMS

What is claimed is:

1. An anatomical drape for covering a treatment area of an anatomical part, the drape comprising an elastomeric material capable of conforming to the contours of the anatomical part and including a curing agent wherein activation of the curing agent causes hardening of the material to at least partially set the drape in a configuration conforming to the anatomical part.

2. An anatomical drape as claimed in claim 1, wherein the elastomeric material of the drape is substantially liquid impermeable and gas permeable, both before and after curing.

3. An anatomical drape as claimed in claim 1 or claim 2, wherein the drape is configured to generally conform to an oral anatomy.

4. An anatomical drape as claimed in claim 3, wherein the drape conforms to a gum ridge anatomy with the drape forming an enclosed protective cover over the gum ridge with optional holes for passage of teeth there through.

5. An anatomical drape as claimed in any one of claims 1 to 4, wherein the curing agent is scattered at intervals throughout the elastomeric material.

6. An anatomical drape as claimed in any one of the preceding claims wherein the curing agent is activated by an external source, such as heat and/or light.

7. An anatomical drape as claimed in claim 6 wherein the curing agent is a light curable agent selected from the group consisting of blended mixtures of acrylate monomers, urethane acrylate oligomers, triacrylate cross linkers, plasticizers, and photo-initiators.

8. An anatomical drape as claimed in any one of the preceding claims wherein one or more treatment material layers are included on at least one surface of the drape.

9. A kits of parts for installing an anatomical drape, the kit comprising a drape according to any one of the preceding claims and a light source, optionally with at least one further drape and/or a therapeutic or other treatment source.

10. A method for the manufacture of an anatomical drape, the method comprising the steps of: (a) adding a soluble additive to an elastomeric material; (b) molding the material to conform

generally to the contours of an anatomical part; (c) adding a solvent to dissolve and remove the additive thereby forming voids in the elastomeric material; and (d) introducing a second additive into at least some of the voids.

11. A method according to claim 10, wherein the soluble additive comprises grit of any desired size for forming voids of a corresponding size.

12. A method according to claim 10 or claim 11, wherein the soluble additive has a low or high melting point to cause flow or allow compression of material into a desired mold to cast the drape into a desired configuration.

13. A method according to any one of claims 10 to 12 wherein the soluble additive is selected from the group consisting of sodium salts, sodium bicarbonate, potassium salts and sugars.

14. A method according to any one of claims 10 to 13 wherein the second additive comprises a curing agent.

15. A method according to any of claims 10 to 14 wherein step (d) comprises spraying, dipping, or injecting of the second additive to allow its introduction into the voids of the material.

16. A method according to claims 10 to 15 wherein the addition and curing of the second additive retains the breathable properties of the drape while preserving its impermeability to fluids.

17. An oral drape for covering a treatment area of an oral cavity, the drape comprising an elastomeric material capable of conforming to the contours of the oral anatomical part and including a curing agent wherein activation of the curing agent causes hardening of the material to at least partially set the drape in a configuration conforming to the anatomical part, the set drape being substantially gas permeable but liquid impermeable.

Intellectual Property Office

Application No:	GB1409780.2	**Examiner:**	Mr Michael Young
Claims searched:	1-9,17	**Date of search:**	15 December 2014

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-9, 17	US 2014/080082 A1 (LOWE) See in particular paras. 0025-0039, 0052-0074, 0085-0087, claims 1, 4, 5, 8, 9-13, 20.
X	1-9, 17	US 4790752 A1 (CHESLAK) See in particular col.2 lines 22-44, col.3 lines 8-22, col.9 line 60 - col.10 line 32.
X	1-9, 17	US 2006/246400 A1 (FISCHER) See in particular paras.0039, 0041, claim 8.
X	1-9,17	WO 2008/137069 A2 (ALIGN TECH.) See in particular, para. 0099, claims 30, 31.
A	4	WO 2013/039906 A1 (MAVRIK) Shows tooth holes, fig.13B.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
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Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61C; B29C

The following online and other databases have been used in the preparation of this search report

WPI EPODOC

Intellectual Property Office

International Classification:

Subclass	Subgroup	Valid From
A61C	0019/06	01/01/2006
B29C	0035/00	01/01/2006